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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,778	11/28/2000	Jeffrey T. Finer	CYTOP009C1	9331

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BEYER WEAVER & THOMAS LLP  
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EXAMINER
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TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34

## Office Action Summary

### Application No.

09/724,778

### Applicant(s)

FINER ET AL.

### Examiner

Tamthom N. Truong

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18,19,65,67,76,82 and 84-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,19,65,67,76,82 and 84-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3-30-04, 9-10-02, 1-7-04, 5-27-03, 10-3-02, 9-10-02,
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### FINAL ACTION

Applicant's amendment of 04-08-04 has been fully considered. Claims 1-17, 20-64, 66, 68-75, 77-81, 83 have been cancelled. Claims 85-91 have been added.

Claims 18, 19, 65, 67, 76, 82, and 84-91 are pending.

The amendment does not address the previous "Scope of Enablement" rejection, and thus, said rejection is maintained herein for claims 18, 19, 65, 67, 76, 82, and 84. Claims 73 and 83 have cancelled, and therefore, the previous rejection of 122/2<sup>nd</sup> has been obviated.

New claims 85-91 raise the following new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 18, 19, 65, 67, 76, 82 and 84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of certain cancers (e.g., lung, breast, ovarian, colon, etc.), does not reasonably provide enablement for the treatment of cancer in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

**The breadth of the claims:** The scope of “cancer” includes cancers of various organs, and tissues, many of which cannot be treated (e.g., liver cancer, pancreatic cancer, etc.).

**The amount of direction or guidance presented:** The specification only provides bioassay for the inhibition of KSP on certain tumor cells such as: lung, breast, ovarian, colon, cervical, leukemia, renal, osteosarcoma, and SF-268. The specification does not show any evidence that the claimed compounds can treat other cancers.

**The state of the prior art:** While many available chemotherapeutic agents are used to treat a number of cancers. They are actually effective in a few cancer such as:

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breast cancer, colon cancer, or ovarian cancer, or lymphoma. There has not been an agent that can effectively treat all kinds of cancer without damaging other normal cell growth.

Thus, with the **unpredictable nature of the art**, and limited guidance in terms of tumor cell lines, the **skilled clinician** would have to carry out undue experimentation to treat diseases other than certain cancers because to use an inhibitor of cellular proliferation for treating all disorders would stop the growth of normal cells as well.

2. **Enablement:** Claims 85-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 85 recites a “*method of inhibiting mitosis in a cell*”, which covers the inhibition of cell division in **all** cell types. Such a method would inhibit the production of erythrocytes as well as many B- and T-lymphocytes which would be detrimental to a patient. The specification does not provide guidance for one skilled in the art to pick and choose a compound (among the four sets of compounds) that would *selectively* inhibit mitosis in certain cells. Therefore, it would require undue experimentation for one skilled in the art to research for a safe and effective compound that can be used in a clinical setting.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 85-91 are rejected under 35 U.S.C. 102(e) as being inherently anticipated by **Baxter et. al.** (US 6,545,005 B1).

On columns 75 and 76, Baxter et. al. (US'005) disclose four compounds (#13, 14, 15, ) which fall within the three quinazolinone formulae having an 'amide' side chain, a 'sulfonamide' side chaine, and a 'di-substituted amino' side chain. That is, the disclosed compounds read on those three formulae (or compounds in claims 85-87, and 89-91) with the following substituents:

- i.  $R_1$  is a substituted aryl;
- ii. One of  $R_2$  and  $R_{2'}$  is a hydrogen, and the other is an alkyl group;
- iii.  $R_3$  and  $R_{3'}$ , each represents a substituted aryl group;
- iv.  $R_{3''}$  is a substituted alkyl group;

- v. R<sub>4</sub> is an alkyl group.

In Figure 32b, compounds # 11, 36, 37, and 38 read on compounds (in claims 85-88) of the quinazolinone formula having an 'amide' side chain with the following substituents:

- vi. R<sub>1</sub> is a substituted aryl;
- vii. One of R<sub>2</sub> and R<sub>2</sub>' is a hydrogen, and the other is an alkyl group;
- viii. R<sub>3</sub> represents R<sub>15</sub>-NH;
- ix. R<sub>4</sub> is an alkyl group.

The disclosed compounds antagonize "hedgehog" activity, which in turn, can inhibit pathological cell proliferation. Although the reference does not explicitly mention "mitosis", it is understood by one skilled in the art that "mitosis" is a cell division process in cell proliferation. Therefore, the reference inherently teaches the methods recited in the instant claims 85-91.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-T (~10 am ~ 8:30 pm) starting from February 22<sup>nd</sup>, 2004.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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June 23, 2004



RICHARD L. RAYMOND  
PRIMARY EXAMINER  
ART UNIT 1624